

**Effectiveness of Methods used by Dental Professionals for the Primary Prevention of
Dental Caries: A Review of the Evidence**

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Abstract:

This paper summarizes and rates the evidence for the effectiveness of methods available to dental professionals for their use in the primary prevention of dental caries. It reviews operator-applied therapeutic agents or materials and patient counseling. Evidence of effectiveness is extracted from published systematic reviews. A search for articles since publication of these reviews was done to provide updates and a systematic review of the caries-inhibiting effects of fluoride varnish in primary teeth is provided. Good evidence is available for the effectiveness of fluoride gel and varnish, chlorhexidine and sealant when used to prevent caries in permanent teeth of children and adolescents. The evidence for effectiveness of fluoride varnish use in primary teeth, chlorhexidine varnish and patient counseling is judged to be insufficient. Use of the four methods reviewed in the paper according to tested protocols and for the populations in which evidence of effect is available can be recommended. However, they may need to be used selectively. Estimates for the number of patients or tooth surfaces needed to treat to prevent a carious event suggest that the additional effects of these professional treatments are low in patients who are at reduced risk for dental caries. The literature on use of these preventive methods in individuals other than school-aged children needs expansion.

Keywords: Caries, prevention, fluoride gels, fluoride varnish, chlorhexidine, pit-and-fissure sealant, counseling. systematic review.

Effective caries-preventive methods for use by dental professionals in caring for their patients, by individuals or by public health practitioners in communities and other population-based program sites have been developed and refined since the introduction of community water fluoridation in the 1940's.¹ The literature on these caries-inhibiting methods is extensive. Preventive strategies have been developed and tested that address all major aspects of the etiology of caries.

This paper summarizes the evidence for the effectiveness of methods available to dental professionals for their use in the primary prevention of dental caries. Its focus is on operator-applied therapeutic agents or materials. Because of the scope of this review and the extensive literature related to the topic, the evidence is extracted mostly from published systematic reviews. Updates of the reviews are provided where appropriate, and a systematic review of the caries-inhibiting effects of fluoride varnish in primary teeth is included.

Individuals have at their disposal many methods that they can use to prevent dental caries. Behaviors such as dental visits, use of fluoride products, use of antimicrobial agents, and oral hygiene and dietary practices can affect caries incidence throughout life. These methods that rely on individual behaviors are not included in the review. Because of the large number of preventive methods available to individuals for use outside the dental office, patient counseling by dental professionals is important. Although not a primary preventive chemotherapeutic agent or material, this paper includes a review of the effectiveness of patient counseling.

With the exception of chlorhexidine, the paper seeks to answer the following question for each of the preventive methods: “Overall, how effective is this agent or activity when used in a typical dental office setting with a typical patient?” The way in which this question is posed implies two underlying premises. Statistically, the answer is derived from the center of the estimate of effectiveness. Second, with the exception of antimicrobial agents, which are designed to be used in patients at high risk for caries, only studies of the general population are included. Other papers based on presentations at the NIH Consensus Conference address the effectiveness of caries preventive methods in high caries risk individuals.^{2, 3}

METHODS

A systematic search of the literature for review papers published in the English language was undertaken in MEDLINE for the period 1980 through October 2000 and in EMBASE for 1988 through June 2000 using the primary search words “caries”, “cariou”, “prevent”, “Meta-analysis” and “review”. The 821 retrieved articles in MEDLINE and 206 in EMBASE were further limited using filters for the specific preventive methods to be included in this review (topical fluorides, chlorhexidine, pit and fissure sealant, health education).

The quality of each systematic review was rated qualitatively using guidelines available in the literature.^{4, 5} It was judged as “excellent”, “good”, or “fair” based on whether the review included four characteristics that would help reduce bias (RCT, search method described, publication bias assessed, heterogeneity assessed) and whether it provided precision estimates for the treatment effect. The strength of the evidence from the systematic reviews was judged as “excellent”, “good” or “poor” according to whether it included RCTs only and the overall quality

assessment. Each systematic review was updated through October 2000 using the same search strategy outlined in the particular publication and where possible, the same inclusion and exclusion criteria.

A systematic review was done as part of this paper on the effectiveness of fluoride varnish in inhibiting caries in primary teeth. Interest in use of this preventive method with preschool-aged children has increased because of the observation that the prevalence of dental caries has not declined in this age group as it has for older children⁶ and the growing awareness of the attractive safety properties of varnishes compared to gels and solutions for very young children.^{7,8} All fluoride varnish papers retrieved from MEDLINE for 1966-2000 using the keywords “topical fluoride” were reviewed and entered into evidence tables if they included assessments of primary tooth caries increments in experimental and control groups.

Each paper identified in the process of updating the published systematic reviews and those included in the fluoride varnish review were scored for quality using the rating forms devised by the Research Triangle Institute-University of North Carolina Evidence-based Practice Center for its review of management of dental caries.⁹ The overall quality score, which can vary from 0 to 100, is based on several items of internal validity and a subjective assessment of internal and external validity. The strength of the evidence of effectiveness for each study was judged as “good”, “fair”, “poor” or “insufficient” according to criteria specified by the Research Triangle Institute-University of North Carolina Evidence-based Practice Center.

Two measures of treatment effect are presented in summary tables. The primary measure of outcome is the Prevented Fraction (PF), or the proportional reduction in dental caries between experimental and control participants, expressed as a percentage.¹⁰ The second measure of effect, the Number Needed to Treat (NNT), is defined as the number of patients who need to be treated in a specified length of time to achieve one additional favorable outcome, usually the prevention of one surface of decay.¹¹ It is the inverse of the Absolute Risk Reduction, which is the arithmetic difference in dental caries outcomes between control and experimental participants. Unlike the PF, the NNT reflects the risk of the event without therapy, and therefore can discern large treatment effects from small ones. The pooled PF and NNT scores for the reviews that included a meta-analysis are included in Table 2. This table also includes these two measures for the update of these reports, as well as their quality score.

RESULTS

Results of Search of the Literature: Close to 40 review papers were identified that focused on methods available for the prevention of dental caries. Systematic reviews were found for topical fluoride gel,¹² fluoride varnish,^{13, 14} chlorhexidine,¹⁵ pit-and-fissure sealant,¹⁶ and patient counseling.¹⁷⁻¹⁹

All in all, these reviews are of good to excellent quality (Table 1). The four operator-applied methods were, in effect, limited to RCTs, mostly with negative controls. Of these four preventive methods, only the review of chlorhexidine did not assess publication bias and only the review of sealants did not test for consistency of treatment effects. The reviews of health promotion interventions are more qualitative, and rated fair to good.

Effectiveness of Topical Fluorides

Fluoride Gels: Topical fluoride gels are in more widespread use by US dental care professionals than solutions, varnishes or foams, although they often are not used according to protocols that have been tested for effectiveness.²⁰ Only APF gels have been tested in controlled clinical trials that most closely reflect current protocols suitable for the dental office.⁷

The systematic review of clinical studies on the caries-inhibiting effects of professional and self-applied fluoride gel treatment¹² included 17 studies (19 comparisons) published between 1965 and 1995.²¹⁻³⁷ Their meta-analysis of these studies provided a pooled estimate of gels caries inhibiting effect of 22 percent (95% CI=18, 25), providing good evidence of their effectiveness in permanent teeth. The nine studies (10 comparisons) of professionally applied gels^{21, 22, 26-28, 31, 33, 35, 37} included in the systematic review by van Rijkom et al.¹² provides an overall average (unweighted) prevented fraction of 18 percent.

The search to update the published review identified two additional fluoride gel studies,^{38, 39} the second of which³⁹ met the inclusion criteria set by authors of the published review. This double-blind, randomized controlled trial of professional flossing with either NaF or SnF gel produced significant caries reductions on interproximal surfaces for SnF only. The intensity of the application, however, does not seem practical for the dental office.

Effectiveness of Fluoride Varnishes: Fluoride varnishes were developed more than 30 years ago with the aim of increasing the caries-inhibiting properties of fluoride by holding it to tooth surfaces in the presence of saliva for longer periods of time than other fluoride products.⁴⁰

Products with two fluoride compounds are available in the United States—five percent sodium fluoride in a resin carrier (2.26% F, 22.6 mg/mL F, 22,600 ppm) and 1percent difluorsilane in polyurethane (0.1% F, 1.0 mg/mL F, 1,000 ppm F).

The available systematic review of the caries-inhibiting effects of varnishes is limited to the effects of 5 percent sodium fluoride (Duraphat) on permanent teeth of children 6-15 years of age.^{13, 14} A search for studies published between 1975 and 1991 netted 30 studies, 13 of which were included in a meta-analysis.⁴¹⁻⁵³ The overall prevented fraction for these studies was estimated by meta-analysis to be 38 percent (95% CI=25, 50). A systematic search to update the review identified 17 clinical studies, of which only one met the inclusion criteria.⁵⁴ Like the results of the meta-analysis, it provides good evidence of effect.

Seven studies of the effectiveness of fluoride varnish when used in primary teeth were found (Table 3).⁵⁵⁻⁶¹ Five of the seven comparisons with controls found no statistically significant results. Only two of the six are randomized controlled trials and they had inconsistent findings.^{56, 58} The one by Holm⁵⁶ is more relevant to the question of caries preventive effects in preschool-aged children because study subjects were 5 years of age at the end of the study and therefore would have some remaining primary incisors to allow testing of the full effects of varnish. However, the evidence for the caries-inhibiting properties for varnishes when used for primary teeth is limited and the evidence for effectiveness is judged to be insufficient.

Effectiveness of Chlorhexidine: Chlorhexidine has substantial antimicrobial properties, particularly against caries-causing bacterial.⁶² Because of these properties it is viewed as an

adjunct to the prevention and control of caries in high-risk individuals. A variety of delivery systems exist, but the only products marketed in the United States are mouthrinses containing 0.12 percent chlorhexidine.

The systematic review of the caries-inhibiting properties of chlorhexidine done by van Rijkom et al.¹⁵ found 24 papers published between 1975 and 1994. Their meta-analysis of the eight randomized controlled trials⁶³⁻⁷⁰ that met their inclusion criteria found a prevented fraction of 46 percent (95% CI=35, 57).

Five of the studies in the published review included evaluation of professionally applied one percent chlorhexidine gel.⁶⁵⁻⁶⁹ All included exposures to professional or individual fluoride regimens in addition to the chlorhexidine gel. Results of these five randomized controlled trials of professional gel applications have an unweighted mean PF of 47 percent, providing good evidence of effect.

The update of the van Rijkom et al.¹⁵ review identified 45 titles and 7 abstracts for further review. Three of these studies, all RCTs of professional applications of chlorhexidine varnish, met the inclusion criteria.⁷¹⁻⁷³ The studies provide mixed evidence of the caries preventive effects of chlorhexidine used as a varnish, and they are judged to provide insufficient evidence of effectiveness.

Effectiveness of Pit-and-Fissure Dental Sealants: The available systematic review of the preventive effects of sealants included 24 studies published from 1975 to 1990.¹⁶ No studies of

visible light cured sealants were included because the Prevented Fraction could not be derived, so the review concentrated on auto polymerized sealant and ultraviolet light polymerized sealant, which is no longer commercially available. A meta-analysis of reports of auto polymerized sealant,⁷⁴⁻⁸⁴ all of which used the half-mouth design, provided a PF of 71.3 percent (95% CI=69.9, 72.9) and thus good evidence for effectiveness.

To update the published review on sealant effectiveness, entries in MEDLINE for the years 1991 to 2000 were reviewed. Titles for 280 entries and 39 abstracts identified five studies with six reports⁸⁵⁻⁹⁰ that met the general inclusion criteria of Lodra et al.¹⁶ The design of most of these studies differs from those included in the published systematic review. Only one uses the half-mouth design.⁹⁰ One of the five is a cohort study,⁸⁵ one a program evaluation using a retrospective cohort design,⁸⁶ and one a community trial.⁸⁷ They also differ from the published review because reapplication of sealant was done in most of them. Other methodological features make these five studies very heterogeneous among themselves. However, these additional studies support the conclusions of effectiveness of auto-polymerized sealant made by Lodra et al.,¹⁶ and provide additional evidence of the effectiveness of resin sealant polymerized by visible light.

Effectiveness of Patient Counseling: Three recent systematic reviews of oral health promotion have been done. Kay and Locker¹⁸ reviewed 18 dental caries studies. Seven of these are randomized controlled trials, but only two were dental clinic based.^{91,92} Based on their review, Kay and Locker¹⁸ concluded that oral health promotion is successful in reducing caries if it brings about the use of fluoride containing agents. However, the two RCTs show conflicting

results in caries reductions. A previous systematic review by these same investigators of studies published between 1982 and 1994 found only four caries studies, which could be evaluated only qualitatively.¹⁷ Their conclusion from this review was that there is no evidence that dental health education interventions affect caries levels. Sprod et al.¹⁹ did not stratify their review according to different oral health problems, so specific conclusions about dental caries are not possible.

A general conclusion from these three systematic reviews is that individual knowledge about oral health can be improved through oral health promotion activities, and that health promotion programs that increase knowledge may also change behaviors, although the causal relationship between knowledge and behavior is weak. The evidence of effectiveness for clinic-based health promotion and educational activities on dental caries of patients is rated as insufficient. The very small number of studies, their poor quality and inconsistent findings provides no evidence on which to rate effectiveness.

DISCUSSION

This review of methods available to dental professionals for the primary prevention of dental caries provides good evidence of effectiveness for fluoride gels and varnish, chlorhexidine and sealant when used to prevent caries in permanent teeth of children and adolescents. The overall preventive effects of professionally applied fluoride gel, fluoride varnish and chlorhexidine on caries increments in exposed children compared to control children are between 22 and 46 percent. The evidence for these treatment effects is based on a reasonable number of randomized controlled trials for each of the methods, and therefore provides the best possible evidence. The synthesis of the literature using meta-analysis provides further support for this

conclusion. Studies also suggest that these professionally applied products can provide added benefits beyond those derived from exposures to self-applied topical fluorides and community water fluoridation. With the exception of chlorhexidine varnish, which was not included in any of the published reviews, studies identified in updating the reviews found no evidence that would contradict this recommendation for the use of these four products.

This review also provides support for a strong recommendation for the use of the four methods reviewed in the paper when they are used according to the tested protocols. However, they may need to be used selectively. Most of the studies were done in the 1970s and 1980s when negative controls were permissible and caries rates were higher than they are today. Estimates for the number of patients or tooth surfaces needed to treat to prevent a dental cavity (1 DMFS) for fluoride gels, fluoride varnishes and sealants suggest that the additional effects of these professional treatments are low in patients who are at reduced risk for dental caries. Using the pooled estimates of caries-inhibiting effects available from the meta-analyses reviewed for this paper, 18 and 11 low caries risk children would need to be treated by gel or varnish per year, respectively, to avert one DMFS. Assuming that the annual increment of decay-affected pit and fissure tooth surfaces is 50 per 1,000, or 5 percent per year⁹³ and using the pooled estimates for caries-inhibiting effects of sealants from the reviewed meta-analysis, 16 tooth surfaces would need to be sealant to avert one DMFS in low risk patients.

For more than a decade, individual investigators and expert panels have recommended that professional topical fluoride use be limited to those individuals with moderate-to-high caries risk^{1, 94-96} The American Dental Association,⁹⁷ Canadian Medical Association⁹⁸ and expert

panels⁹⁹ all have recommended that sealants be used selectively for high-risk individuals in clinical settings. Clinical data suggest that sealants have a greater benefit when placed in permanent teeth with incipient caries^{86, 100} or in remaining molars of individuals who already have one permanent molar restored.¹⁰¹ To date, however, no balanced randomized controlled trials have evaluated the effectiveness of sealants according to the caries risk of individuals.

Evidence for the effectiveness of methods for use in the dental office for the prevention of dental caries is limited for children younger than six years of age and for adults. A single randomized controlled trial of the effects of fluoride varnish on primary teeth of children younger than 6 years of age demonstrated substantial treatment effects, but the other six studies of primary teeth showed conflicting results and limit our ability to determine their true caries-inhibiting effects in young children. Therefore, the evidence of effectiveness for fluoride varnish is insufficient to recommend for or against its use in the preschool-aged child. In a recent review of the safety and benefits of fluoride varnishes, Bawden⁷ concluded that the evidence does suggest that it is safe and practical for use in young children, with enough evidence to conduct trials to determine effectiveness.

This literature search turned up only five reviews of caries prevention with fluorides in adults¹⁰²⁻¹⁰⁶ and only one concentrated on evidence of effectiveness.¹⁰² The small number of studies in adults and their variation make it difficult to estimate effectiveness of caries-inhibiting methods when used in adults.

Finally, this review does not include use of combinations of professionally applied preventive methods, such as in-office topical fluoride products and pit-and-fissure sealants. Yet we can assume that if single interventions have marginal benefit in low-risk subjects and thus may not be needed, then multiple interventions likewise are not needed. On the other hand, evidence for effectiveness of multiple preventive methods used in high-risk individuals of all ages is limited and research is needed. Continued overall progress in caries reductions in the general population will require that those at greatest risk to disease be provided with access to comprehensive and proven preventive methods.

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Table 1: Characteristics of Systematic Reviews included in Paper by Primary Dental Caries Prevention Method

Review	Preventive Method	Years Included	Major Inclusion Criteria	Validity of Results				Treatment Effect	
				RCT Only	Search Method Described	Publ Bias Assessed	Heterogeneity Assessed	Measure of Magnitude	Precision Provided
van Rijkom et al., 1998 ¹²	Fluoride gel	1965-95	General pop. Negative control No other prevent methods except toothpaste Permanent teeth 6-15-years old Surface-level caries incidence	Yes	Yes	Yes	Yes	Prevented Fraction	Yes
Helfenstein & Steiner, 1994 ¹³ Helfenstein & Steiner, 1994 ¹⁴	Fluoride varnish	1975-91	Duraphat Caries increment Cont vs. test gr. Permanent teeth 'Normal' children Statistics for Tx effects	No	Yes	Yes	Yes	Prevented Fraction	Yes
van Rijkom et al., 1996 ¹⁵	Chlor-hexidine	1986-94	Permanent teeth 11-15-years old All caries risk gr. Surface-level caries incidence Tx \geq 1 year	Yes	Yes	No	Yes	Prevented Fraction	Yes
Llodra et al., 1993 ¹⁶	Pit-and-fissure sealant	1975-90	Original data Permanent teeth No other prevent measures Statistics for Tx effects	NR	Yes	Yes	Yes	Prevented Fraction	Yes

Table 1 (Con't): Characteristics of Systematic Reviews included in Paper by Primary Dental Caries Prevention Method

Review	Preventive Method	Years Included	Major Inclusion Criteria	Validity of Results				Treatment Effect	
				RCT Only	Search Method Described	Publ Bias Assessed	Heterogeneity Assessed	Measure of Magnitude	Precision Provided
Sprod et al., 1996 ¹⁹	Counseling	1982-95	Aim of promoting oral health Evaluative & descriptive Measured knowledge, attitudes, behaviors	No	Yes	No	No	Qualitative	No
Kay & Locker, 1996 ¹⁷	Counseling	1982-94	Original data Quantitative data on outcomes	No	Yes	No	No	Qualitative	No
Kay & Locker, 1998 ¹⁸	Counseling	1979-95	Not Reported	No	Yes	No	No	Pooled, weighted absolute DMF	Yes

++ Not Reported but all of auto polymerized sealant studies used half-mouth design.

+ Relaxed inclusion criteria so studies that did not provide a measure of sampling variation were included.

+++For 7 RCTs included in review.

Table 2: Summary of Evidence of Effectiveness of Preventive Methods in the Primary Prevention of Dental Caries in Permanent Teeth, Published Systematic Reviews and their Updates

Study	Agent	Number Studies in Review	Quality Score	Prevented Fraction % (95% CI)	Number Needed to Treat+
Fluoride Gel					
van Rijkom et al., 1998 review ¹²	1.23% APF	19	Excellent	22 (18, 25)	18
Gisselsson et al., 1999 ³⁹	1% SnF 1% NaF	-	67	39 (-0.3, 60 30 (N.S.))	3
Fluoride Varnish					
Helfenstien & Steiner, 1994 Review ¹³	5% NaF	8	Good	38 (19, 57)	11
Helfenstien & Steiner, 1994 Review ¹⁴	5% NaF	14	Good	38 (25, 50)	11
Zimmer et al., 1999 ⁵⁴	5% NaF	-	50	37 (4, 69)	8
Chlorhexidine					
van Rijkom et al., 1996 ¹⁵	Rinse, Gel, Toothpaste	8	Good	46 (35, 57)	1
Bratthall et al., 1995 ⁷¹	1% CHX varnish	-	28	25 (N.R.)	-
Fennis-le et al., 1998 ⁷²	40% CHX varnish	-	61	-9 (N.S.) [low risk]	-
Fennis-le et al., 1998 ⁷²	40% CHX varnish	-	61	33 (3, 63) [high risk]	3
Forgie et al., 2000 ⁷³	10% CHX varnish	-	84	-5 (N.S.)++	-
Pit-and Fissure Sealant					
Llodra et al., 1993 review ¹⁶	Auto-polymerized	10	Good	71 (69, 72)	24
Simonsen, 1991 ⁸⁵	Auto-Polymerized	-	44	62 (50, 75)	33
Heller et al., 1995 ⁸⁶	Visible light polymerized	-	45	68 (41, 96)	23
Songpaisan et al., 1995 ⁸⁷	Auto-Polymerized		67	92 (66, 119)	2
Bravo et al., 1996 ⁸⁸	Visible light polymerized	-	76	76 (61, 92)	24
Bravo et al., 1997 ⁸⁹	Visible light polymerized	-	78	69 (55, 82)	12
Leal et al., 1998 ⁹⁰	Auto-polymerized	-	39	66 (18, 115)	68

Table 2 (Con't): Footnotes

+ Number of individuals needed to treat (NNT) per year to prevent one carious event. NNT for reviews of gel, varnish and chlorhexidine calculated assuming an annual caries increment of 0.25 and the pooled PF. For review of sealants, NNT calculated assuming an annual increment of pit-and-fissure surface caries of 5%.

++ Active varnish group compared to placebo varnish group with D₃ threshold for caries diagnosis.

N.R. = Not reported.

N.S.= Not statistically significant.

Table 3. Studies of the Caries-Preventive Effects of Fluoride Varnish in Primary Teeth

Study Reference	Quality Score (%)	Treatment	Prevented Fraction %	P-Value	Number Needed to Treat
Murray et al. ⁵⁵	73	2.2% F ⁻ (Duraphat) twice a year	7.4	N.S.	-
Holm ⁵⁶	62	2.2% F ⁻ (Duraphat) twice a year	43.8	<0.01	1.2
Grodzka et al. ⁵⁷	50	2.2% F ⁻ (Duraphat) twice a year	5.3	N.S.	-
Clark et al. ⁵⁸	73	2.2% F ⁻ (Duraphat) twice a year	10.3	N.S.	-
		0.7% F ⁻ (Fluor Protector) twice a year	6.9	N.S.	-
Frostell et al. ^{59 +}	39	2.2% F ⁻ (Duraphat) twice a year	37.2	<0.01	1.5
Twetman et al. ⁶⁰	56	0.1% F ⁻ (Fluor Protector) twice a year	30.0	<0.05	4.3
Petersson et al. ^{61 ++}	56	0.1% F ⁻ (Fluor Protector) twice a year	6.4	N.S.	-

+ Study included six experimental groups: sucrose and invert sugar groups with and without Duraphat; nonparticipants in sugar trial randomly assigned to Duraphat and control groups. Comparison is for subjects not participating in sugar clinical trial. Sucrose and invert sugar groups showed no differences according to Duraphat exposures.

++ A subanalysis found statistically significant differences found in interproximal surfaces and those with caries at baseline.

N.S. = Difference between experimental and control group not statistically significant.